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Our Case No. 8627-1391
Client Ref. No. PA-5511-PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David G. Burton et al.)
Serial No.: 10/593,376) Examiner: Sarah K. Webb
Filing Date: July 9, 2007) Group Art Unit No.: 3731
For: MEDICAL BALLOON WITH) Confirmation No.: 8852
ENLARGED TRANSITIONAL RADII)

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Examiner's Answer dated March 2, 2011, Applicants submit this Reply Brief in support of the appeal of the final rejection of claims 1, 3-4, 12-16, 22 and 24-25.

Argument

A. Claims 1, 3-4, 12-16, 22 and 24-25 are not indefinite.

The Examiner has indicated in the Interview Summary dated January 7, 2011 that Applicants' amendments have overcome the Examiner's rejections under 35 U.S.C. § 112 ¶ 2. Therefore, these rejections are moot.

B. Claims 1, 3-4, 12-16, 22 and 24-25 are not obvious over Lee in view of Bleam.

The Examiner's conclusion of obviousness is far too broad and is not supported by the disclosures of Lee and Bleam. Specifically, the Examiner admits that "the references do not explicitly discuss enlarging the radii of the balloon transitions." (Answer at 7). However, the Examiner then leaps to a generalized conclusion that "the prior art as a whole teaches the general concepts of forming a balloon with smooth, gradual transition zones between the working length and proximal and distal tapered sections." (Answer at 7).

In fact, Applicants' claimed inventions and Lee and Bleam relate to two distinctly different things, which the Examiner admits in part and hedges in part. With respect to Lee, the Examiner's positions are inconsistent and do not accurately represent what Lee actually discloses. The Examiner states that Lee discloses that the "tapered regions (48 and 50) provide smooth transitions from the working diameter in section (44) to the small diameter of the neck regions (42 and 62)." However, to be clear, what Lee is referring to is specifically the tapers 48, 50, not the transitions between the tapers 48, 50 and the working diameter section 44. Mr. Burton explains this in his declaration, but the Examiner refused to give Mr. Burton's declaration any weight. (Answer at 7 ("considered to be irrelevant")).

Nonetheless, the specification of Lee makes clear that the smooth transition referred to therein relates to the "distal taper 50." (¶ [0022]). This is made even more clear in Figure 3 of Lee where reference number 50 points to the taper of the balloon between the working diameter section 44 and the neck 46, not the transition between the taper 50 and the working diameter 44. (Compare location of working length-to-taper

transition 252 in Figure 2 of Applicants' specification). Indeed, the Examiner seems to implicitly recognize that Lee relates to something different by admitting that Lee "fails to disclose the specific radii of the transitions when the balloon is in a deflated state as set forth in these claims." (Answer at 4). The reason for this omission is that Lee doesn't relate to the claimed transitions, but instead, relates to the taper only.

The Examiner's description of Lee further confirms that Lee does not relate to the transitions claimed by Applicants. Specifically, the Examiner argues that Lee discloses rounded transitions because Lee "teaches that the tapers of the balloon should be substantially flat in the deflated state for easier maneuvering and less trauma to a patient's vasculature." (Answer at 5). However, this does not prove the Examiner's conclusion. As Applicants explained in their specification, medical balloons are often not capable of obtaining the pre-inflation "folded configuration" after being inflated inside the body. Applicants' inventions seek to improve upon this problem by providing specifically sized radii at the working length-to-taper transition. However, Lee does not even specifically refer to what happens to the balloon when it is deflated after being inflated. Lee merely states that the tapers 48, 50 lie flat when the balloon is not pressurized. (¶ [0023]). And yet, it is apparent from the specification of Lee that Lee's tapers 48, 50 lie flat because of the shape of the tapers themselves and not because of a specific radius at the transitions, which is not even referred to in Lee.

Further, although the Examiner asserts that the rejection is not based upon measurements from the drawings of Lee because "Lee provides no dimensions related to the tapered regions or transition zones," (Answer at 8) it is apparent that this is the only basis upon which the Examiner can conceivably be relying upon, because there is nothing else in the specification of Lee that even refers to the transitions that Applicants have claimed. The basis for the Examiner's position is made quite clear on page 4 of the Examiner's Answer, where immediately below a reproduction of Figure 1 of Lee, the Examiner concludes that "Lee illustrates all of the transitions as having smooth, rounded edges and teaches that the tapered regions should be smooth in order to allow the balloon to traverse stenosis." However, reliance solely upon an interpretation of the drawings of Lee is improper. Indeed, even the figures in Lee are not consistent with each other. (Compare Figures 1 and 3). And while reliance solely upon figures in a

patent specification is at best dubious in an ordinary case, Applicants' own specification warns against this type of comparison in this case. As explained, even a conventional balloon will have smooth transitions when the balloon is inflated. (Pg. 14-15; Figure 13B).

Thus, Lee fails to relate to the transitions that Applicants have claimed. Therefore, Lee cannot provide a motivation to modify the radius of the claimed transitions because Lee relates to a different part of the balloon, i.e., only the tapers themselves. Not only does Lee relate to something different, but Lee cannot even remotely suggest the specific ranges of radii that Applicants have claimed, and which, the Examiner merely brushes aside as "common knowledge." (Answer at 8).

With respect to Bleam, the Examiner admits that Bleam "does not explicitly describe an increase of transition radii" and instead "teaches that smaller taper angles and larger taper length can reduce these frictional forces." (Answer at 5). Thus, even by the Examiner's admissions, Bleam relates to the tapers like Lee, not to the transitions between the tapers and the working diameter. Indeed, the Examiner goes on to admit that the "Examiner recognizes that the angle of the taper may not impact the transition radii." (Answer at 8). Therefore, based upon the Examiner's admissions, it is apparent that Bleam adds nothing to Lee because in fact both Lee and Bleam relate to the tapers and not to the claimed transitions.

Conclusion

Because Lee and Bleam do not disclose the claimed transitions between a balloon taper and the working length diameter, and the Examiner has not established a sufficient reason for combining Lee and Bleam to achieve the claimed limitations, Applicants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejections of claims 1, 3-4, 12-16, 22 and 24-25.

Respectfully submitted,

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